

108TH CONGRESS
2D SESSION

S. 720

AN ACT

To amend title IX of the Public Health Service Act to provide for the improvement of patient safety and to reduce the incidence of events that adversely effect patient safety.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Patient Safety and
5 Quality Improvement Act of 2004”.

1 **SEC. 2. FINDINGS AND PURPOSES.**

2 (a) FINDINGS.—Congress makes the following find-
3 ings:

4 (1) In 1999, the Institute of Medicine released
5 a report entitled *To Err is Human* that described
6 medical errors as the eighth leading cause of death
7 in the United States, with as many as 98,000 people
8 dying as a result of medical errors each year.

9 (2) To address these deaths and injuries due to
10 medical errors, the health care system must identify
11 and learn from such errors so that systems of care
12 can be improved.

13 (3) In their report, the Institute of Medicine
14 called on Congress to provide legal protections with
15 respect to information reported for the purposes of
16 quality improvement and patient safety.

17 (4) The Health, Education, Labor, and Pen-
18 sions Committee of the Senate held 4 hearings in
19 the 106th Congress and 1 hearing in the 107th Con-
20 gress on patient safety where experts in the field
21 supported the recommendation of the Institute of
22 Medicine for congressional action.

23 (5) Myriad public and private patient safety ini-
24 tiatives have begun. The Quality Interagency Coordi-
25 nation Taskforce has recommended steps to improve
26 patient safety that may be taken by each Federal

1 agency involved in health care and activities relating
2 to these steps are ongoing.

3 (6) The research on patient safety unequivocally
4 calls for a learning environment, rather than a
5 punitive environment, in order to improve patient
6 safety.

7 (7) Voluntary data gathering systems are more
8 supportive than mandatory systems in creating the
9 learning environment referred to in paragraph (6) as
10 stated in the Institute of Medicine's report.

11 (8) Promising patient safety reporting systems
12 have been established throughout the United States
13 and the best ways to structure and use these sys-
14 tems are currently being determined, largely through
15 projects funded by the Agency for Healthcare Re-
16 search and Quality.

17 (9) Many organizations currently collecting pa-
18 tient safety data have expressed a need for legal pro-
19 tections that will allow them to review protected in-
20 formation and collaborate in the development and
21 implementation of patient safety improvement strat-
22 egies. Currently, the State peer review protections
23 are inadequate to allow the sharing of information to
24 promote patient safety.

25 (b) PURPOSES.—It is the purpose of this Act to—

1 (1) encourage a culture of safety and quality in
 2 the United States health care system by providing
 3 for legal protection of information reported volun-
 4 tarily for the purposes of quality improvement and
 5 patient safety; and

6 (2) ensure accountability by raising standards
 7 and expectations for continuous quality improve-
 8 ments in patient safety.

9 **SEC. 3. AMENDMENTS TO PUBLIC HEALTH SERVICE ACT.**

10 Title IX of the Public Health Service Act (42 U.S.C.
 11 299 et seq.) is amended—

12 (1) in section 912(c), by inserting “, in accord-
 13 ance with part C,” after “The Director shall”;

14 (2) by redesignating part C as part D;

15 (3) by redesignating sections 921 through 928,
 16 as sections 931 through 938, respectively;

17 (4) in 934(d) (as so redesignated), by striking
 18 the second sentence and inserting the following:

19 “Penalties provided for under this section shall be
 20 imposed and collected by the Secretary using the ad-
 21 ministrative and procedural processes used to impose
 22 and collect civil money penalties under section
 23 1128A of the Social Security Act (other than sub-
 24 sections (a) and (b), the second sentence of sub-
 25 section (f), and subsections (i), (m), and (n)), unless

1 the Secretary determines that a modification of pro-
 2 cedures would be more suitable or reasonable to
 3 carry out this subsection and provides for such
 4 modification by regulation.”;

5 (5) in section 938(1) (as so redesignated), by
 6 striking “921” and inserting “931”; and

7 (6) by inserting after part B the following:

8 **“PART C—PATIENT SAFETY IMPROVEMENT**

9 **“SEC. 921. DEFINITIONS.**

10 “In this part:

11 “(1) NON-IDENTIFIABLE INFORMATION.—

12 “(A) IN GENERAL.—The term ‘non-identi-
 13 fiable information’ means, with respect to infor-
 14 mation, that the information is presented in a
 15 form and manner that prevents the identifica-
 16 tion of a provider, a patient, or a reporter of
 17 patient safety data.

18 “(B) IDENTIFIABILITY OF PATIENT.—For
 19 purposes of subparagraph (A), the term ‘pre-
 20 sented in a form and manner that prevents the
 21 identification of a patient’ means, with respect
 22 to information that has been subject to rules
 23 promulgated pursuant to section 264(c) of the
 24 Health Insurance Portability and Accountability
 25 Act of 1996 (42 U.S.C. 1320d–2 note), that the

1 information has been de-identified so that it is
 2 no longer individually identifiable health infor-
 3 mation as defined in such rules.

4 “(2) PATIENT SAFETY DATA.—

5 “(A) IN GENERAL.—The term ‘patient
 6 safety data’ means—

7 “(i) any data, reports, records, memo-
 8 randa, analyses (such as root cause anal-
 9 yses), or written or oral statements that
 10 are—

11 “(I) collected or developed by a
 12 provider for reporting to a patient
 13 safety organization, provided that they
 14 are reported to the patient safety or-
 15 ganization within 60 days;

16 “(II) requested by a patient safe-
 17 ty organization (including the con-
 18 tents of such request), if they are re-
 19 ported to the patient safety organiza-
 20 tion within 60 days;

21 “(III) reported to a provider by a
 22 patient safety organization; or

23 “(IV) collected by a patient safe-
 24 ty organization from another patient

1 safety organization, or developed by a
 2 patient safety organization;
 3 that could result in improved patient safe-
 4 ty, health care quality, or health care out-
 5 comes; or

6 “(ii) any deliberative work or process
 7 with respect to any patient safety data de-
 8 scribed in clause (i).

9 “(B) LIMITATION.—

10 “(i) COLLECTION.—If the original
 11 material from which any data, reports,
 12 records, memoranda, analyses (such as
 13 root case analyses), or written or oral
 14 statements referred to in subclause (I) or
 15 (IV) of subparagraph (A)(i) are collected
 16 and is not patient safety data, the act of
 17 such collection shall not make such original
 18 material patient safety data for purposes
 19 of this part.

20 “(ii) SEPARATE DATA.—The term ‘pa-
 21 tient safety data’ shall not include infor-
 22 mation (including a patient’s medical
 23 record, billing and discharge information
 24 or any other patient or provider record)
 25 that is collected or developed separately

1 from and that exists separately from pa-
 2 tient safety data. Such separate informa-
 3 tion or a copy thereof submitted to a pa-
 4 tient safety organization shall not itself be
 5 considered as patient safety data. Nothing
 6 in this part, except for section 922(f)(1),
 7 shall be construed to limit—

8 “(I) the discovery of or admissi-
 9 bility of information described in this
 10 subparagraph in a criminal, civil, or
 11 administrative proceeding;

12 “(II) the reporting of information
 13 described in this subparagraph to a
 14 Federal, State, or local governmental
 15 agency for public health surveillance,
 16 investigation, or other public health
 17 purposes or health oversight purposes;
 18 or

19 “(III) a provider’s recordkeeping
 20 obligation with respect to information
 21 described in this subparagraph under
 22 Federal, State, or local law.

23 “(3) PATIENT SAFETY ORGANIZATION.—The
 24 term ‘patient safety organization’ means a private or

1 public entity or component thereof that is currently
2 listed by the Secretary pursuant to section 924(c).

3 “(4) PATIENT SAFETY ORGANIZATION ACTIVITIES.—The term ‘patient safety organization activities’ means the following activities, which are
4 deemed to be necessary for the proper management
5 and administration of a patient safety organization:
6

7 “(A) The conduct, as its primary activity,
8 of efforts to improve patient safety and the
9 quality of health care delivery.
10

11 “(B) The collection and analysis of patient
12 safety data that are submitted by more than
13 one provider.

14 “(C) The development and dissemination
15 of information to providers with respect to improving patient safety, such as recommendations, protocols, or information regarding best
16 practices.
17

18 “(D) The utilization of patient safety data
19 for the purposes of encouraging a culture of
20 safety and of providing direct feedback and assistance to providers to effectively minimize patient risk.
21
22
23

1 “(E) The maintenance of procedures to
2 preserve confidentiality with respect to patient
3 safety data.

4 “(F) The provision of appropriate security
5 measures with respect to patient safety data.

6 “(G) The utilization of qualified staff.

7 “(5) PERSON.—The term ‘person’ includes Fed-
8 eral, State, and local government agencies.

9 “(6) PROVIDER.—The term ‘provider’ means—
10 “(A) a person licensed or otherwise author-
11 ized under State law to provide health care
12 services, including—

13 “(i) a hospital, nursing facility, com-
14 prehensive outpatient rehabilitation facil-
15 ity, home health agency, hospice program,
16 renal dialysis facility, ambulatory surgical
17 center, pharmacy, physician or health care
18 practitioner’s office, long term care facility,
19 behavior health residential treatment facil-
20 ity, clinical laboratory, or health center; or

21 “(ii) a physician, physician assistant,
22 nurse practitioner, clinical nurse specialist,
23 certified registered nurse anesthetist, cer-
24 tified nurse midwife, psychologist, certified
25 social worker, registered dietitian or nutri-

1 tion professional, physical or occupational
 2 therapist, pharmacist, or other individual
 3 health care practitioner; or

4 “(B) any other person specified in regula-
 5 tions promulgated by the Secretary.

6 **“SEC. 922. PRIVILEGE AND CONFIDENTIALITY PROTEC-**
 7 **TIONS.**

8 “(a) PRIVILEGE.—Notwithstanding any other provi-
 9 sion of Federal, State, or local law, patient safety data
 10 shall be privileged and, subject to the provisions of sub-
 11 section (c)(1), shall not be—

12 “(1) subject to a Federal, State, or local civil,
 13 criminal, or administrative subpoena;

14 “(2) subject to discovery in connection with a
 15 Federal, State, or local civil, criminal, or administra-
 16 tive proceeding;

17 “(3) disclosed pursuant to section 552 of title
 18 5, United States Code (commonly known as the
 19 Freedom of Information Act) or any other similar
 20 Federal, State, or local law;

21 “(4) admitted as evidence or otherwise disclosed
 22 in any Federal, State, or local civil, criminal, or ad-
 23 ministrative proceeding; or

24 “(5) utilized in a disciplinary proceeding
 25 against a provider.

1 “(b) CONFIDENTIALITY.—Notwithstanding any other
 2 provision of Federal, State, or local law, and subject to
 3 the provisions of subsections (c) and (d), patient safety
 4 data shall be confidential and shall not be disclosed.

5 “(c) EXCEPTIONS TO PRIVILEGE AND CONFIDEN-
 6 TIALITY.—Nothing in this section shall be construed to
 7 prohibit one or more of the following uses or disclosures:

8 “(1) Disclosure by a provider or patient safety
 9 organization of relevant patient safety data for use
 10 in a criminal proceeding only after a court makes an
 11 in camera determination that such patient safety
 12 data contains evidence of a wanton and criminal act
 13 to directly harm the patient.

14 “(2) Voluntary disclosure of non-identifiable pa-
 15 tient safety data by a provider or a patient safety
 16 organization.

17 “(d) PROTECTED DISCLOSURE AND USE OF INFOR-
 18 MATION.—Nothing in this section shall be construed to
 19 prohibit one or more of the following uses or disclosures:

20 “(1) Disclosure of patient safety data by a per-
 21 son that is a provider, a patient safety organization,
 22 or a contractor of a provider or patient safety orga-
 23 nization, to another such person, to carry out pa-
 24 tient safety organization activities.

1 “(2) Disclosure of patient safety data by a pro-
2 vider or patient safety organization to grantees or
3 contractors carrying out patient safety research,
4 evaluation, or demonstration projects authorized by
5 the Director.

6 “(3) Disclosure of patient safety data by a pro-
7 vider to an accrediting body that accredits that pro-
8 vider.

9 “(4) Voluntary disclosure of patient safety data
10 by a patient safety organization to the Secretary for
11 public health surveillance if the consent of each pro-
12 vider identified in, or providing, such data is ob-
13 tained prior to such disclosure. Nothing in the pre-
14 ceding sentence shall be construed to prevent the re-
15 lease of patient safety data that is provided by, or
16 that relates solely to, a provider from which the con-
17 sent described in such sentence is obtained because
18 one or more other providers do not provide such con-
19 sent with respect to the disclosure of patient safety
20 data that relates to such nonconsenting providers.
21 Consent for the future release of patient safety data
22 for such purposes may be requested by the patient
23 safety organization at the time the data is sub-
24 mitted.

1 “(5) Voluntary disclosure of patient safety data
2 by a patient safety organization to State of local
3 government agencies for public health surveillance if
4 the consent of each provider identified in, or pro-
5 viding, such data is obtained prior to such disclo-
6 sure. Nothing in the preceding sentence shall be con-
7 strued to prevent the release of patient safety data
8 that is provided by, or that relates solely to, a pro-
9 vider from which the consent described in such sen-
10 tence is obtained because one or more other pro-
11 viders do not provide such consent with respect to
12 the disclosure of patient safety data that relates to
13 such nonconsenting providers. Consent for the fu-
14 ture release of patient safety data for such purposes
15 may be requested by the patient safety organization
16 at the time the data is submitted.

17 “(e) CONTINUED PROTECTION OF INFORMATION
18 AFTER DISCLOSURE.—

19 “(1) IN GENERAL.—Except as provided in para-
20 graph (2), patient safety data that is used or dis-
21 closed shall continue to be privileged and confiden-
22 tial as provided for in subsections (a) and (b), and
23 the provisions of such subsections shall apply to
24 such data in the possession or control of—

1 “(A) a provider or patient safety organiza-
 2 tion that possessed such data before the use or
 3 disclosure; or

4 “(B) a person to whom such data was dis-
 5 closed.

6 “(2) EXCEPTION.—Notwithstanding paragraph
 7 (1), and subject to paragraph (3)—

8 “(A) if patient safety data is used or dis-
 9 closed as provided for in subsection (c)(1), and
 10 such use or disclosure is in open court, the con-
 11 fidentiality protections provided for in sub-
 12 section (b) shall no longer apply to such data;
 13 and

14 “(B) if patient safety data is used or dis-
 15 closed as provided for in subsection (c)(2), the
 16 privilege and confidentiality protections pro-
 17 vided for in subsections (a) and (b) shall no
 18 longer apply to such data.

19 “(3) CONSTRUCTION.—Paragraph (2) shall not
 20 be construed as terminating or limiting the privilege
 21 or confidentiality protections provided for in sub-
 22 section (a) or (b) with respect to data other than the
 23 specific data used or disclosed as provided for in
 24 subsection (c).

25 “(f) LIMITATION ON ACTIONS.—

1 “(1) PATIENT SAFETY ORGANIZATIONS.—Ex-
2 cept to enforce disclosures pursuant to subsection
3 (c)(1), no action may be brought or process served
4 against a patient safety organization to compel dis-
5 closure of information collected or developed under
6 this part whether or not such information is patient
7 safety data unless such information is specifically
8 identified, is not patient safety data, and cannot oth-
9 erwise be obtained.

10 “(2) PROVIDERS.—An accrediting body shall
11 not take an accrediting action against a provider
12 based on the good faith participation of the provider
13 in the collection, development, reporting, or mainte-
14 nance of patient safety data in accordance with this
15 part. An accrediting body may not require a provider
16 to reveal its communications with any patient safety
17 organization established in accordance with this
18 part.

19 “(g) REPORTER PROTECTION.—

20 “(1) IN GENERAL.—A provider may not take an
21 adverse employment action, as described in para-
22 graph (2), against an individual based upon the fact
23 that the individual in good faith reported
24 information—

1 “(A) to the provider with the intention of
2 having the information reported to a patient
3 safety organization; or

4 “(B) directly to a patient safety organiza-
5 tion.

6 “(2) ADVERSE EMPLOYMENT ACTION.—For
7 purposes of this subsection, an ‘adverse employment
8 action’ includes—

9 “(A) loss of employment, the failure to
10 promote an individual, or the failure to provide
11 any other employment-related benefit for which
12 the individual would otherwise be eligible; or

13 “(B) an adverse evaluation or decision
14 made in relation to accreditation, certification,
15 credentialing, or licensing of the individual.

16 “(h) ENFORCEMENT.—

17 “(1) PROHIBITION.—Except as provided in sub-
18 sections (c) and (d) and as otherwise provided for in
19 this section, it shall be unlawful for any person to
20 negligently or intentionally disclose any patient safe-
21 ty data, and any such person shall, upon adjudica-
22 tion, be assessed in accordance with section 934(d).

23 “(2) RELATION TO HIPAA.—The penalty pro-
24 vided for under paragraph (1) shall not apply if the
25 defendant would otherwise be subject to a penalty

1 under the regulations promulgated under section
 2 264(c) of the Health Insurance Portability and Ac-
 3 countability Act of 1996 (42 U.S.C. 1320d-2 note)
 4 or under section 1176 of the Social Security Act (42
 5 U.S.C. 1320d-5) for the same disclosure.

6 “(3) EQUITABLE RELIEF.—

7 “(A) IN GENERAL.—Without limiting rem-
 8 edies available to other parties, a civil action
 9 may be brought by any aggrieved individual to
 10 enjoin any act or practice that violates sub-
 11 section (g) and to obtain other appropriate eq-
 12 uitable relief (including reinstatement, back
 13 pay, and restoration of benefits) to redress such
 14 violation.

15 “(B) AGAINST STATE EMPLOYEES.—An
 16 entity that is a State or an agency of a State
 17 government may not assert the privilege de-
 18 scribed in subsection (a) unless before the time
 19 of the assertion, the entity or, in the case of
 20 and with respect to an agency, the State has
 21 consented to be subject to an action as de-
 22 scribed by this paragraph, and that consent has
 23 remained in effect.

24 “(i) RULE OF CONSTRUCTION.—Nothing in this sec-
 25 tion shall be construed to—

1 “(1) limit other privileges that are available
2 under Federal, State, or local laws that provide
3 greater confidentiality protections or privileges than
4 the privilege and confidentiality protections provided
5 for in this section;

6 “(2) limit, alter, or affect the requirements of
7 Federal, State, or local law pertaining to informa-
8 tion that is not privileged or confidential under this
9 section;

10 “(3) alter or affect the implementation of any
11 provision of section 264(c) of the Health Insurance
12 Portability and Accountability Act of 1996 (Public
13 Law 104–191; 110 Stat. 2033), section 1176 of the
14 Social Security Act (42 U.S.C. 1320d–5), or any
15 regulation promulgated under such sections;

16 “(4) limit the authority of any provider, patient
17 safety organization, or other person to enter into a
18 contract requiring greater confidentiality or dele-
19 gating authority to make a disclosure or use in ac-
20 cordance with subsection (c) or (d); and

21 “(5) prohibit a provider from reporting a crime
22 to law enforcement authorities, regardless of whether
23 knowledge of the existence of, or the description of,
24 the crime is based on patient safety data, so long as

1 the provider does not disclose patient safety data in
2 making such report.

3 **“SEC. 923. PATIENT SAFETY NETWORK OF DATABASES.**

4 “(a) IN GENERAL.—The Secretary shall maintain a
5 patient safety network of databases that provides an inter-
6 active evidence-based management resource for providers,
7 patient safety organizations, and other persons. The net-
8 work of databases shall have the capacity to accept, aggre-
9 gate, and analyze nonidentifiable patient safety data vol-
10 untarily reported by patient safety organizations, pro-
11 viders, or other persons.

12 “(b) NETWORK OF DATABASE STANDARDS.—The
13 Secretary may determine common formats for the report-
14 ing to the patient safety network of databases maintained
15 under subsection (a) of nonidentifiable patient safety data,
16 including necessary data elements, common and consistent
17 definitions, and a standardized computer interface for the
18 processing of such data. To the extent practicable, such
19 standards shall be consistent with the administrative sim-
20 plification provisions of Part C of title XI of the Social
21 Security Act.

22 **“SEC. 924. PATIENT SAFETY ORGANIZATION CERTIFI-**
23 **CATION AND LISTING.**

24 “(a) CERTIFICATION.—

1 “(1) INITIAL CERTIFICATION.—Except as pro-
 2 vided in paragraph (2), an entity that seeks to be a
 3 patient safety organization shall submit an initial
 4 certification to the Secretary that the entity intends
 5 to perform the patient safety organization activities.

6 “(2) DELAYED CERTIFICATION OF COLLECTION
 7 FROM MORE THAN ONE PROVIDER.—An entity that
 8 seeks to be a patient safety organization may—

9 “(A) submit an initial certification that it
 10 intends to perform patient safety organization
 11 activities other than the activities described in
 12 subparagraph (B) of section 921(4); and

13 “(B) within 2 years of submitting the ini-
 14 tial certification under subparagraph (A), sub-
 15 mit a supplemental certification that it per-
 16 forms the patient safety organization activities
 17 described in subparagraphs (A) through (F) of
 18 section 921(4).

19 “(3) EXPIRATION AND RENEWAL.—

20 “(A) EXPIRATION.—An initial certification
 21 under paragraph (1) or (2)(A) shall expire on
 22 the date that is 3 years after it is submitted.

23 “(B) RENEWAL.—

24 “(i) IN GENERAL.—An entity that
 25 seeks to remain a patient safety organiza-

tion after the expiration of an initial certification under paragraph (1) or (2)(A) shall, within the 3-year period described in subparagraph (A), submit a renewal certification to the Secretary that the entity performs the patient safety organization activities described in section 921(4).

“(ii) TERM OF RENEWAL.—A renewal certification under clause (i) shall expire on the date that is 3 years after the date on which it is submitted, and may be renewed in the same manner as an initial certification.

“(b) ACCEPTANCE OF CERTIFICATION.—Upon the submission by an organization of an initial certification pursuant to subsection (a)(1) or (a)(2)(A), a supplemental certification pursuant to subsection (a)(2)(B), or a renewal certification pursuant to subsection (a)(3)(B), the Secretary shall review such certification and—

“(1) if such certification meets the requirements of subsection (a)(1), (a)(2)(A), (a)(2)(B), or (a)(3)(B), as applicable, the Secretary shall notify the organization that such certification is accepted; or

1 “(2) if such certification does not meet such re-
 2 quirements, as applicable, the Secretary shall notify
 3 the organization that such certification is not accept-
 4 ed and the reasons therefor.

5 “(c) LISTING.—

6 “(1) IN GENERAL.—Except as otherwise pro-
 7 vided in this subsection, the Secretary shall compile
 8 and maintain a current listing of patient safety or-
 9 ganizations with respect to which the Secretary has
 10 accepted a certification pursuant to subsection (b).

11 “(2) REMOVAL FROM LISTING.—The Secretary
 12 shall remove from the listing under paragraph (1)—

13 “(A) an entity with respect to which the
 14 Secretary has accepted an initial certification
 15 pursuant to subsection (a)(2)(A) and which
 16 does not submit a supplemental certification
 17 pursuant to subsection (a)(2)(B) that is accept-
 18 ed by the Secretary;

19 “(B) an entity whose certification expires
 20 and which does not submit a renewal applica-
 21 tion that is accepted by the Secretary; and

22 “(C) an entity with respect to which the
 23 Secretary revokes the Secretary’s acceptance of
 24 the entity’s certification, pursuant to subsection
 25 (d).

1 “(d) REVOCATION OF ACCEPTANCE.—

2 “(1) IN GENERAL.—Except as provided in para-
 3 graph (2), if the Secretary determines (through a re-
 4 view of patient safety organization activities) that a
 5 patient safety organization does not perform one of
 6 the patient safety organization activities described in
 7 subparagraph (A) through (F) of section 921(4), the
 8 Secretary may, after notice and an opportunity for
 9 a hearing, revoke the Secretary’s acceptance of the
 10 certification of such organization.

11 “(2) DELAYED CERTIFICATION OF COLLECTION
 12 FROM MORE THAN ONE PROVIDER.—A revocation
 13 under paragraph (1) may not be based on a deter-
 14 mination that the organization does not perform the
 15 activity described in section 921(4)(B) if—

16 “(A) the listing of the organization is
 17 based on its submittal of an initial certification
 18 under subsection (a)(2)(A);

19 “(B) the organization has not submitted a
 20 supplemental certification under subsection
 21 (a)(2)(B); and

22 “(C) the 2-year period described in sub-
 23 section (a)(2)(B) has not expired.

24 “(e) NOTIFICATION OF REVOCATION OR REMOVAL
 25 FROM LISTING.—

1 “(1) SUPPLYING CONFIRMATION OF NOTIFICA-
 2 TION TO PROVIDERS.—Within 15 days of a revoca-
 3 tion under subsection (d)(1), a patient safety organi-
 4 zation shall submit to the Secretary a confirmation
 5 that the organization has taken all reasonable ac-
 6 tions to notify each provider whose patient safety
 7 data is collected or analyzed by the organization of
 8 such revocation.

9 “(2) PUBLICATION.—Upon the revocation of an
 10 acceptance of an organization’s certification under
 11 subsection (d)(1), or upon the removal of an organi-
 12 zation from the listing under subsection (c)(2), the
 13 Secretary shall publish notice of the revocation or
 14 removal in the Federal Register.

15 “(f) STATUS OF DATA AFTER REMOVAL FROM LIST-
 16 ING.—

17 “(1) NEW DATA.—With respect to the privilege
 18 and confidentiality protections described in section
 19 922, data submitted to an organization within 30
 20 days after the organization is removed from the list-
 21 ing under subsection (c)(2) shall have the same sta-
 22 tus as data submitted while the organization was
 23 still listed.

24 “(2) PROTECTION TO CONTINUE TO APPLY.—If
 25 the privilege and confidentiality protections de-

1 scribed in section 922 applied to data while an orga-
 2 nization was listed, or during the 30-day period de-
 3 scribed in paragraph (1), such protections shall con-
 4 tinue to apply to such data after the organization is
 5 removed from the listing under subsection (c)(2).

6 “(g) DISPOSITION OF DATA.—If the Secretary re-
 7 moves an organization from the listing as provided for in
 8 subsection (c)(2), with respect to the patient safety data
 9 that the organization received from providers, the organi-
 10 zation shall—

11 “(1) with the approval of the provider and an-
 12 other patient safety organization, transfer such data
 13 to such other organization;

14 “(2) return such data to the person that sub-
 15 mitted the data; or

16 “(3) if returning such data to such person is
 17 not practicable, destroy such data.

18 **“SEC. 925. TECHNICAL ASSISTANCE.**

19 “The Secretary, acting through the Director, may
 20 provide technical assistance to patient safety organiza-
 21 tions, including convening annual meetings for patient
 22 safety organizations to discuss methodology, communica-
 23 tion, data collection, or privacy concerns.

1 **“SEC. 926. PROMOTING THE INTEROPERABILITY OF**
 2 **HEALTH CARE INFORMATION TECHNOLOGY**
 3 **SYSTEMS.**

4 “(a) DEVELOPMENT.—Not later than 36 months
 5 after the date of enactment of the Patient Safety and
 6 Quality Improvement Act of 2004, the Secretary shall de-
 7 velop or adopt voluntary standards that promote the elec-
 8 tronic exchange of health care information.

9 “(b) UPDATES.—The Secretary shall provide for the
 10 ongoing review and periodic updating of the standards de-
 11 veloped under subsection (a).

12 “(c) DISSEMINATION.—The Secretary shall provide
 13 for the dissemination of the standards developed and up-
 14 dated under this section.

15 **“SEC. 927. AUTHORIZATION OF APPROPRIATIONS.**

16 “There is authorized to be appropriated such sums
 17 as may be necessary to carry out this part.”.

18 **SEC. 4. STUDIES AND REPORTS.**

19 (a) IN GENERAL.—The Secretary of Health and
 20 Human Services shall enter into a contract (based upon
 21 a competitive contracting process) with an appropriate re-
 22 search organization for the conduct of a study to assess
 23 the impact of medical technologies and therapies on pa-
 24 tient safety, patient benefit, health care quality, and the
 25 costs of care as well as productivity growth. Such study
 26 shall examine—

1 (1) the extent to which factors, such as the use
 2 of labor and technological advances, have contrib-
 3 uted to increases in the share of the gross domestic
 4 product that is devoted to health care and the im-
 5 pact of medical technologies and therapies on such
 6 increases;

7 (2) the extent to which early and appropriate
 8 introduction and integration of innovative medical
 9 technologies and therapies may affect the overall
 10 productivity and quality of the health care delivery
 11 systems of the United States; and

12 (3) the relationship of such medical technologies
 13 and therapies to patient safety, patient benefit,
 14 health care quality, and cost of care.

15 (b) REPORT.—Not later than 18 months after the
 16 date of enactment of this Act, the Secretary of Health and
 17 Human Services shall prepare and submit to the appro-
 18 priate committees of Congress a report containing the re-
 19 sults of the study conducted under subsection (a).

Passed the Senate July 22, 2004.

Attest:

Secretary.

108TH CONGRESS
2D Session

S. 720

AN ACT

To amend title IX of the Public Health Service Act to provide for the improvement of patient safety and to reduce the incidence of events that adversely effect patient safety.